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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,481	03/31/2004	Rajesh A. Patel	304142000900	8558

25226 7590 11/29/2007
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EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
11/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/815,481	PATEL ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) *6,11,12,21,24-48,56 and 57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-10,15-20,22,23,49-55 and 58-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12-14-04,4-24-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicants' election of Group I, claims 1 – 28 and 49 – 56 without traverse is acknowledged. In view of the newly added claims, Group I now includes claims 1 – 28, 49 – 61. Applicants also elected lisuride as the species of dopamine agonist, reading on claims 1 – 5, 7 – 20, 22 – 28, 49 – 55 and 57 – 61, NSAID as the anti-inflammatory, reading on claims 1 – 11, 13, 15 – 24, 26, and 49 – 61, Parkinsons's disease as the disease, reading on claims 1 – 28 and 49 – 61, and an anti-inflammatory and dopamine agonist that are in separate devices, which according to Applicants reads on claims 1 – 28, 49 – 56, and 58 – 61. However, it is noted that claim 11 requires "an anti-inflammatory agent encapsulated within said matrix", said matrix being the matrix of claim 1. Claim 1 states that the matrix is part of the device containing the dopamine agonist. As such, Claim 11 actually recites a dopamine agonist and NSAID combined in the same device, which does not read on the elected species. Claims 13 – 14 depend on claim 11, and therefore also do not read on the elected species. For the same reason, Claims 24 and 26 also do not read on the elected species. Pursuant to election, claims 1 – 5, 7 – 10, 15 – 20, 22, 23, 49 – 55, and 58 – 61 are discussed on the merits below, and claims 6, 11, 12, 21, 24 – 48, 56, and 57 are withdrawn.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 4, 7 – 10, 15 – 19, and 22 – 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Sabel et al., "Extended Levodopa Release from a

Subcutaneously Implanted Polymer Matrix in Rats", of record. The rejection of claims 3, 15 and 18 is evidenced by Freese et al., "Controlled Release of Dopamine from Polymeric Brain Implant: *In Vitro* Characterization", and the Elvax® Specialty EVA Resins disclosures.

Note that this rejection reads on the generic species of dopamine agonists, but does not read on the elected species of lisuride.

Claim 1 requires an implantable device comprising a dopamine agonist, a biocompatible nonerodale polymeric matrix wherein the dopamine agonist is encapsulated in the matrix and here the implant provides sustained release through the matrix pores resulting in a plasma level of at least 0.01 ng/ml. Claim 2 requires an EVA copolymer, and claim 3 specifies that the copolymer be about 33%vinyl acetate. Claim 4 recites the amount of dopamine agonist, and claim 7 requires sustained release for at least 3 months. Claim 8 is a product by process claim, where the method of making is not afforded patentable weight. Claim 9 recites the size of the device, and claim 10 further limits the amount of active released per day. Claims 16 – 29 and 22 – 23 are similar to claims 1 – 4 and 7 – 10, except that claim 16 requires 0.1 mg or more of dopamine agonist to be released per day.

The Sabel reference teaches and EVA matrix containing 70% L-Dopa (a dopamine agonist, also called levodopa). (p 715, Methods section). The matrix is 15mm x 30mm x 2mm in size (p 715, methods section), commensurate with the requirements of the claims. The matrix contains pores through which the L-Dopa dissolves into an aqueous environment (p 715, Results section). The release of the L-

Dopa is commensurate with that required by instant claims. Figure 2 (A) and (B) show sustained release over more than 3 months, release of more than 1 mg per day, and release of more than 0.01 ng /ml plasma.

With regard to claims 3 and 18, which require about 33% vinyl acetate in the EVA copolymer, the reference is silent on the amount of vinyl acetate, but notes that the procedure used is the same as that in a previous reference, namely the Freese reference. The Freese reference teaches that the EVA copolymer was purchased from DuPont as ELVAX® 40P. According to the ELVAX disclosure, it does not appear that the 40P line is still available, however, the other ELVAX 40 products (40L-03 and 40W) have 40% vinyl acetate. It is understood that the Sabel reference also used EVA with about 40% vinyl acetate, which reads on instantly claimed about 33% vinyl acetate.

With regard to Claim 15, an antioxidant is understood to be inherently part of the composition, because according to the ELVAX disclosure, all ELVAX 40 materials include a small amount of BHT as an antioxidant, and Sabal makes no mention of removing the antioxidant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 49 – 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sabel et al.

The teachings of Sabel have been discussed.

What is lacking is a teaching of a kit with instructions.

It would be prima facie obvious to a person of ordinary skill in the art at the time of the invention to package the devices of claims 1 – 4, 7 – 10, 15 – 19, and 22 – 23 as a kit with one or more devices per kit and with instructions for use of the devices. The motivation comes from the desire to sell, ship, or use one or more devices in conjunction with treating one or more patients under the care of the same physician, or under treatment at the same facility or in the same geographical location. A kit is a convenient way to package more than one device together for transport to the same physician, facility, or geographical location. Including instructions is obvious because the maker of the device would want the end-user to know how to use the device, and would thus communicate appropriate instructions to the end-user by way of instructions.

Claims 5, 20, 59 60 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sabel et al., "Extended Levodopa Release from a Subcutaneously

Implanted Polymer Matrix in Rats", of record as applied to claims 1 – 4, 7 – 10, 16 – 19, 22 – 23 and 49 – 55 above and in view of US 5,128,145 to Edgren.

The teachings of Sabel have been discussed.

What is lacking is a teaching of lisuride.

Edgren teaches that lisuride and levodopa are equivalent anti-Parkinson drugs, and that both are ergot derivatives (Example 3).

It would be prima facie obvious to a person of ordinary skill in the art at the time of the invention to substitute lisuride for levodopa in the implant of Sabal. The motivation comes from Edgren who teaches that the two are both recognized in the art for the same purpose, namely treating Parkinsons's disease.

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over 5, 20, 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sabel et al., "Extended Levodopa Release from a Subcutaneously Implanted Polymer Matrix in Rats", of record as applied to claims 1 – 4, 7 – 10, 16 – 19, 22 – 23 and 49 – 55 above and in view of WO 98/20864 (the '864 reference).

The claim recites the kit of claim 49 further comprising an anti-inflammatory agent encapsulated within a biocompatible, nonerodable polymer matrix that does not comprise the dopamine agonist.

The teachings of Sabel have been discussed.

What is lacking is the anti-inflammatory.

The '864 reference teaches the use of non-steroidal anti-inflammatory agents for treatment of Parkinson's disease (abstract).

It would be prima facie obvious to a person of ordinary skill in the art at the time of the invention to include the NSAIDs of '864 reference in a kit with the implants of Sabel. The motivation is to include a second treating agent for Parkinsons, a disease treatable with Sabel's implant. It would be further obvious to include '864's NSAIDs in an implant similar to that of Sabel, because such implants are recognized to be useful in delivering anti-Parkinson's medication. In order to override possible incompatibilities between the drugs, the artisan would use separate devices for the dopamine agonist and the NSAID.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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